

16/4

AMENDMENT TRANSMITTAL LETTER (Large Entity)

Applicant(s): Roman M. Barabolak et al.

NOV 04 2002

Docket No.

112703-211

Serial No.
10/035,320Filing Date
November 8, 2001Examiner
S. RoseGroup Art Unit
1614

Invention: ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING SAME

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	24 -	24 =	0	x \$18.00	\$0.00
INDEP. CLAIMS	3 -	3 =	0	x \$84.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$0.00

- No additional fee is required for amendment.
- Please charge Deposit Account No. in the amount of
A duplicate copy of this sheet is enclosed.
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- Any patent application processing fees under 37 CFR 1.17.



Dated: October 30, 2002

Signature

Robert M. Barrett (Reg. No. 30,142)

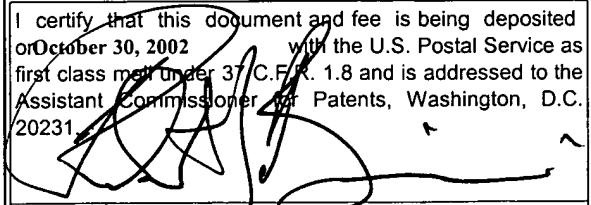
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Applicants: Barabolak et al.
Appl. No.: 10/035,320
Filed: November 8, 2001
Title: ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING
SAME
Art Unit: 1614
Examiner: S. Rose
Docket No.: 112703-211

Commissioner for Patents
Washington, DC 20231

STICK
#7
11/9/02

RESPONSE TO OFFICE ACTION

SIR:

Please enter the following Response in the above-identified patent application.

REMARKS

This Response is submitted in response to the Office Action mailed on September 9, 2002.

In the Office Action, Claims 1, 2, 4, 5, 15, 19, and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,236,699 (“*Libin I*”). Claims 1-7, 9-11, 13, 15-17, and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,487,902 (“*Andersen*”). Claims 1, 2, 5-7, 9, 13-16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,380,530 (“*Hill*”), in view of *Libin I*. Claims 1, 2, 5-7, 9, 13-16, and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hill* in view of U.S. Patent No. 5,711,961 (“*Reiner*”) and U.S. Patent No. 5,248,508 (“*Reed*”).

In the Office Action, Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 10 of U.S. Patent No. 6,355,265 in view of *Libin I*. Moreover, Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as

being unpatentable over Claims 10, 12 and 29 of U.S Patent No. 6,322,806 in view of *Libin I*. Claims 1-22 are further rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 12, 17, and 26 of U.S. Patent No. 6,290,985 in view of *Libin I*. With respect to the double patenting rejections, Applicants have already stated that they will file a suitable terminal disclaimer upon the notice of allowable subject matter.

At the outset, Applicant again takes issue with the Patent Office's seemingly endless use of cumulative rejections based upon multiple references which makes it difficult for Applicants to respond to the Office Action.

In the Office Action, Claims 1, 2, 4, 5, 15, 19 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Libin I*. Applicants respectfully request reconsideration and submit this rejection is improper for reasons set forth below.

As previously argued, “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1981) (emphasis added). Moreover, “The identical invention must be shown in complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989) (emphasis added) Yet in spite of the above, the Patent Office continues to rely on the Merck Index to support this anticipation rejection. Indeed, Applicant submits that the Patent Office’s reliance on extrinsic evidence in this case is clearly improper. It is established case law that extrinsic evidence may not be used to “expand the meaning of terms and phrases used in the reference relied upon as anticipatory of the claimed subject matter.” *In re Baxter Travenol Labs.*, 952 F.2d 388 (Fed. Cir. 1991)(emphasis added). Here, it is clear that the Patent Office is attempting to expand the meaning of Tween 20, which is described only as a solubilizer in *Libin*, to also include being an emulsifier using extrinsic evidence i.e., the Merck Index.

It is clear that *Libin I* fails to disclose each and every feature as required by independent Claims 1 and 15. Independent Claim 1 requires an anti-plaque emulsion that includes an emulsifier, triclosan, and a surfactant. Independent Claim 15 requires a method for reducing plaque that includes the step of orally applying to the mouth an emulsion which includes an emulsifier, triclosan, and a surfactant.

As previously argued, *Libin I* fails to disclose the emulsion features of independent Claims 1 and 15. Nowhere does *Libin I* disclose an emulsion or its use in relation to its anti-plaque mouth rinse. Applicants question how the Patent Office can rely on *Libin I* where *Libin I* discloses a solubilizer that is utilized in a sufficient amount to solubilize triclosan. *See, Libin I*, Claim 1, col. 1 at lines 53-60. In this regard, *Libin I* emphasizes solubilizing, not emulsifying triclosan. Moreover, as discussed above the Patent Office is not permitted to expand the meaning of the solubilizer disclosed in *Libin* to also mean an emulsifier. It is clear that *Libin* is using Tween 20 only as a solubilizer not as an emulsifier. While it is perhaps arguable that Tween 20 is also useful as an emulsifier, the reference clearly does not disclose using it as one. Moreover, the Examiner is not permitted to use extrinsic evidence to characterize Tween 20 as an emulsifier when the reference is only describing it as a solubilizer. As noted above, extrinsic evidence is not allowable to “expand the meaning of terms in a reference.” *See Id.*

Based on the above, the Patent Office’s rejection of Claims 1, 2, 4, 5, 15 and 19 and 23 is clearly improper. Applicants submit that *Libin I* fails to anticipate these claims. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 1-7, 9-11, 13, 15-17 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Andersen*. The Patent Office essentially asserts that *Andersen* discloses each and every feature of the rejected claims.

Applicants submit that the Patent Office again incorrectly relies on *Andersen* as an anticipatory reference. The Examiner’s position that “they do not have to state that their surfactants are emulsifiers, if extrinsic evidence (Merck Index) establishes that such encompassed species of nonionic surfactants to be used are emulsifiers.” is clearly contrary to established law. *See, Office Action*, p. 8-9. As discussed above, the Examiner is not permitted to expand the meaning of terms within a reference using extrinsic evidence.

Andersen, like *Libin I*, requires a solubilizing agent to solubilize the active agent, such as triclosan, in order to control the release of said active agent. *See, Andersen*, Claim 1, col. 10 at line 57-61. Further, *Andersen* clearly makes a distinction between the use of an emulsifier as compared to solubilizers. Again, while it might be arguable that

these solubilizers may also be emulsifiers, it is clearly not described as so in the *Anderson* reference. Moreover, extrinsic evidence is not permitted to expand the meaning of terms in a reference.

Accordingly, in view of the fact that *Andersen* fails to disclose each and every feature of the rejected claims, Applicants submit that *Andersen* fails to anticipate Claims 1-7, 9-11, 13, 15-17 and 19-21. Accordingly, Applicants respectfully request that the rejection of these claims under 35 U.S.C. § 102(b) be withdrawn.

In the Office Action, Claims 1, 2, 5-7, 9, 13-16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hill*. The Patent Office relies on *Libin I* to remedy the deficiencies of *Hill*. Applicants submit that this rejection is improper.

As previously argued, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so, either in the references themselves or in the knowledge generally available to one ordinarily skilled in the art. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The mere fact that the references can normally be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

The Patent Office admits that *Hill* fails to teach or suggest the combination of an emulsifier and a surfactant as required by the rejected claims. Further, *Libin I* cannot be used to remedy the deficiencies of *Hill*. The Patent Office incorrectly relies on *Libin I* as providing a motivation or suggestion to replace the single surfactant or single emulsifier of *Hill* with the combination thereof. Moreover, *Hill* provides no such motivation to combine *Hill* and *Libin I*.

Even if combinable, *Libin I* fails to provide such teaching or suggestion as previously discussed. Nowhere does *Libin I* discuss emulsifiers, let alone the combination of emulsifiers and surfactants. The clear emphasis of *Libin I* is to solubilize agents, such as triclosan, in order to enhance anti-bacterial activity. See, *Libin I*, col. 3, lines 53-60. Therefore, *Hill* and *Libin I*, alone or in combination, fail to teach or suggest each and every feature of the rejected claims.

Based on the fact that *Hill* and *Libin I*, alone or in combination, fail to teach or suggest every feature of the rejected claims, Applicants submit that *Hill* and *Libin I* fail to

render obvious Claims 1, 2, 5-7, 9, 13-16 and 19. Accordingly, Applicants respectfully request that the rejection of Claims 1, 2, 5-7, 9 13-16 and 19 under 35 U.S.C. § 103(a) be withdrawn.

The Patent Office has additionally rejected Claims 1, 2, 5-7, 9, 13-16, and 19 under 35 U.S.C. § 103(a) as being unpatentable over *Hill* in view of U.S. Patent No. 5,711,961 ("Reiner") and U.S. Patent No. 5,248,508 ("Reed"). Applicants respectfully submit that the rejection is improper.

As set forth in detail above, Applicants respectfully assert that the *Hill* reference does not teach or suggest the use of a nonionic surfactant as an emulsifier as is the case with Applicants' claimed invention. Moreover, it is clear that neither *Reiner* nor *Reed* remedy the deficiencies of *Hill*. None of the cited references provide any teaching or suggestion of an anti-plaque emulsion which contains an emulsifier, triclosan, and a surfactant like that of the claimed invention.

Therefore, it is clear that *Hill* alone or in further combination with *Reiner* and *Reed*, does not render obvious the present invention. Accordingly, Applicants respectfully request this rejection under 35 U.S.C. § 103(a) be withdrawn.

Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,



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